

EXHIBIT B TO GENERAL EXPERT REPORT
OF DEBRA FROMER, MD

List of Materials Reviewed (Updated March 28, 2016)

Publicly Sourced Documents:

1. ACOG - (FAQ081) Frequently Asked Questions in Urinary Incontinence
2. ACOG (1995) technical bulletin: Urinary Incontinence. No. 213 - Oct. 1995 (Replaces No. 100, Jan. 1987)
3. ACOG (2005) Practice Bulletin 63 Clinical Management Guidelines for Obstetrician-Gynecologists - Urinary Incontinence in Women
4. ACOG 2011 Committee Opinion 513 – Vaginal Placement of Synthetic Mesh for Pelvic Organ Prolapse
5. ACOG 2011 May FAQ 012 Pelvic Support Problems
6. ACOG 2013 Dec FAQ Pelvic Organ Prolapse
7. ACOG AUGS Joint Position Statement on Uncomplicated SUI-CO 603 (June 2014)
8. ACOG Patient Information Sheet (FAQ166) - Frequently Asked Questions in Surgery for Stress Urinary Incontinence (2011)
9. ACOG Practice Bulletin Number 155 November 2015 (Replaces Practice Bulliten 63, June 2005)
10. ACOG Practice Bulletin Summary Number 155 November 2015 (Replaces Practice Bulliten 63, June 2005)
11. AUA - Monograph on SUI (2011)
12. AUA (2011) Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary
13. AUA (2011) Position Statement on the Use of Vaginal Mesh for the Repair of Pelvic Organ Prolapse
14. AUA (2013) SUI Patient Guide
15. AUA Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of SUI (2013)

16. AUA SUI PocketGuide for Physicians
17. AUA Update AUA SUI Guidelines- Appendices A11 & A16 re Complications (2012)
18. AUA/SUFU Guideline Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults 2012|Amended 2014
19. AUA: American Urological Association Education and Research. Guideline for the surgical management of female stress urinary incontinence: 2009 Update. Linthicum (MD): American Urological Association Education and Research, Inc.: 2009. 44p.
20. AUGS (2013)Position Statement on Restrictions of Surgical Options for Pelvic Floor Disorders
21. AUGS June 2014 Committee Opinion 603 – Evaluation of Uncomplicated Stress Urinary Incontinence in Women Before Surgical Treatement
22. AUGS SUFU Patient FAQs MUS for SUI 2014 Mar 12
23. AUGS SUFU Provider FAQs MUS for SUI 2014 Mar 12
24. AUGS-SUFU MUS Position Statement on Mesh Midurethral Slings for SUI, Jan 3, 2014
25. British Association of Urological Surgeons-BAUS-Synthetic Vaginal Tapes for Stress Incontinence
26. EAU - TVT-O for the treatment of female stress
27. EAU Guidelines on Surgical Treatment of Urinary Incontinence - Midurethral sling Lucas 2012
28. FDA Executive Summary: Surgical Mesh for Treatment of Women With Pelvic Organ Prolapse & Stress Urinary Incontinence: Obstetrics & Gynecology Devices Advisory Committee Meeting Sept. 8-9, 2011
29. FDA Labeling Device Guidance/Blue Book Memo
30. FDA Position Statement re Considerations about Surgical Mesh for SUI, March 27, 2013
31. FDA Presentation - FDA Perspectives on Surgical Mesh for Stress Urinary Incontinence (SUI) - Sept 9, 2010 Pressley
32. FDA Public Health Notification - 2008 Oct. 20
33. FDA Public Health Notification - 2011 July 11
34. FDA's May 2014 Response to Public Citizen

35. ICS Factsheets 2013 Edition - SUI - p 13 2nd paragraph regarding use of the midurethral sling as the treatment of choice
36. ICS/IUGA 2011 graft complications standard definitions (<http://www.ics.org/complication>)
37. IUGA (2011) - Stress Urinary Incontinence: A Guide for Women
38. IUGA (July 2014) Position Statement on Mid-Urethral Slings for Stress Urinary Incontinence
39. IUGA 2011 Pelvic Organ Prolapse: A guide for women
40. IUGA Position Statement on Mid-Urethral Slings for Stress Urinary Incontinence
41. NICE Guideline-Management of urinary incontinence in women (Sept 2013)
42. Oxford Levels of Evidence Pyramid for Practitioners
43. Premarin Advertisement
44. SUFU 2015 February Winter Meeting Abstracts

Medical Literature:

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16. Altman (2007) Short Term Outcome After Transvaginal Mesh Repair Of Pelvic Organ Prolapse. *Int Urogynecol J*
17. Altman (2009) Sexual dysfunction after trocar-guided transvaginal mesh repair of Pelvic Organ Prolapse. *Obstetrics & Gynecology*. Vol 113 No 1 January 2009
18. Altman (2011) Anterior Colporrhaphy vs Transvaginal Mesh for Pelvic Organ Prolapse *N Engl J Med* 2011; 364:1826-36
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2. Ducheyne, Paul
3. Elliot, Daniel (& materials cited in footnotes of expert report)
4. Iakovlev, Vladimir
5. Jordi, Howard
6. Kenton, Kimberly
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Company Documents:

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5. 2003 - Gynecare TVT: Tension-free Support for Incontinence General Professional Education Presentation Slides [ETH.MESH.00373310-88]
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8. 2009 - The Science of 'What's Left Behind...' Evidence & Follow-Up of Mesh Use for SUI by Dr. Doug Grier [ETH.MESH.03751819]
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73. Email from Hinoul re South Africa, TVTO sheaths getting stuck upon removal [ETH.MESH.1210987-95]
74. Email from O’Bryan re GYNECARE TVT Obturator System – FDA [ETH.MESH.6882641-2]
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79. Gynecare TVT Obturator System Sales Materials [ETH.MESH.161953-54]
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Deposition Transcripts & Exhibits:

1. Elliot, Daniel
2. Iakovlev, Dr. Vladimir
3. Nager, Charles
4. Rosenzweig, Bruce
5. Toglia, Marc

I also reviewed all materials and articles cited in my expert report, or supplements thereto, which are not included in this Exhibit B.